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Dated: August 18, 2004

Signature: Shawn P. Foley  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT XIII  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Warrell et al.

Application No.: 10/758,993

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### **REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley  
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Registration No.: 33,071  
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### INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

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08/25/2004 EAREGAY1 00000020 121095 10758993

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<b>TRADEMARK OFFICE</b> Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/758,993
<i>(Use as many sheets as necessary)</i>				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

<b>0 U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA**	US-132,275-B1	10-15-1872	Gettings		
AB**	US-232,807	10-05-1886	Dennett		
AC**	US-3,700,498	10-24-1972	Kanazawa et al.		
AD**	US-4,497,780	02-05-1985	Barin et al.		
AE**	US-5,759,837	06-02-1998	Kuhajda et al.		
AF**	US-2002/0183385	12-05-2002	Ellison et al.		
AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong		
AH**	US-6,770,304	08-03-2004	Warrell et al.		
AI**	US-2003/0099719	05/2003	Warrell et al.		
AJ**	US-6,723,351	04-20-2004	Warrell et al.		
AK**	US-6,773,792	05-11-2004	Lu		

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	JP-51-88620		03-08-1976		
BB	WO-95/01789		01-19-1995		
BC	CN-1133725		10-23-1996		
BD	CN-1131037		09-18-1996		
BE	CN-1122700		05-22-1996		
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BG	CN-1119113		03-27-1996		
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BJ	CN-1079391		12-15-1993		
BK	WO-94/02103		02-03-1994		
BL	FR-2 539 993		03-31-1994		
BM	DE-43 17 331		12-01-1994		
BN	WO-95/22336		08-24-1995		
BO	LV-11667		06-20-1997		
BP	WO-94/02108		02-03-1994		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878			
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.			

Examiner Signature		Date Considered	
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				Application Number	10/758,993
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				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

		A.M.A. 97(1):3-5, 1931	
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	CD	NEUBAUER, "Arsenical cancer: a review", Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
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	CJ	Arsenic, Environmental Health Criteria, 18, Geneva: WHO, 1981	
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	CL	QI and BI, "Method for Removing As <sub>2</sub> O <sub>3</sub> from Realgar, Chung Yao Tung Pao, 8(5):21-22, 1983	
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	CP	SHIMOTSUURA et al., "Studies on the Antineoplastic Actions of As <sub>2</sub> O <sub>3</sub> ", Shikwa Gakuho, 86:1237-1253, 1986	
	CQ	YAMAMOTO et al., "Tumorigenicity of Inorganic Arsenic Compounds Following Intratracheal Instillations to the Lungs of Hamsters", Int. J. Cancer 40:220-223, 1987	
	CR	LEE et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988	
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	CB1	ANDRE et al., "The PML and PML/RAR $\alpha$ . Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996	
	CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991	

Examiner Signature		Date Considered	
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<p>Substitute for form 1449A/B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	10/758,993
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				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996	
CE1	CHEN et al., "Use of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As <sub>2</sub> O <sub>3</sub> Exerts Dose-Dependent Dual Effects on APL Cells", Blood 89(9):3345-3353, 1997 ©The American Society of Hematology 1997	
CF1	CHUNG et al., "Influence for Carcinoma Cell and Lymphatic Cell of Acetyl Arsonate", Yakhak Hoeji 40(5):599-607, 1996 (Abstract Only)	
CG1	DE THE "L'oxyde d'arsenic: apres l'acide retinoique, un nouveau traitement cible dela leucemie algue promyelocytaire" Medecine/Sciences, 13:867-71, 1997	
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CK1	GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996	
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CP1	LU et al., "Study of Reaglar in the Treatment of Acute Promyelocytic Leukemia (APL)-a pilot clinical and laboratory study on 32 Patients", China-Korea Medical Conference '97, 1997	
CQ1	MERVIS, "Ancient Remedy Performs New Tricks", Science 273:578, 1996	
CR1	NEUBAUER, "Arsenic Cancer: A Review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol., Suppl. 13, p. 363-65, 1989	
CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990	
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CW1	SOIGNET et al., "Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine 339:19, 1998. ©Massachusetts Medical Society 1998	
CX1	TRELEAVEN et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, 10:343-345, 1993	
CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.	
CZ1	WANG et al., "Studies on Chemically Preventing Leukemia", Ghung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989	
CA2	XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995	

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Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
	CE2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 patients", J. Harbin Medical Univ. 29(3):243, 1995	
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	CG2	ZHU et al., "Arsenic-induced PML Targeting Onto Nuclear Bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci. 94:3978-3983, 1997, ©The National Academy of Sciences of the USA 1997	
	CH2	"Letter on Historical Facts Regarding the Development of Ai Ling No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of Its Mechanism", Heilongjiang Branch of the Chinese Medical Association, Mar. 27, 1998.	
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	CK2	WANG et al., "Arsenic and the Treatment of Leukemia", J Harbin Medical Univ., vol. 31, No. 5, Oct. 1997	
	CL2	SMORENBURG et al., "Randomized Cross-Over Evaluation of Body-Surface Area-Based Dosing Versus Flat-Fixed Dosing of Paclitaxel", J. Clin. Oncology, 21:197-202 (2003)	
	CM2	VOISEN et al., "Extrapolation of Animal Toxicity to Humans: Interspecies Comparisons in Drug Development", Regulatory Toxicology and Pharmacology, 12:107-116 (1990)	
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	CQ2	AU et al., "Arsenic Trioxide in Comparison with Chemotherapy and Bone Marrow Transplantation for the Treatment of Relapsed Acute Promyelocytic Leukaemia", Annals of Oncology, 14:752-757 (2003)	
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